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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,278	08/10/2000	Gholam-Reza Zadno-Azizi	PERCUS.1CP2C1	7079

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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/636,278	ZADNO-AZIZI ET AL.
	Examiner	Art Unit
	Patricia M Bianco	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 8/10/00; 8/27/01.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 43-64 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 43-64 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> .

**DETAILED ACTION**

***Response to Preliminary Amendments***

1. A preliminary amendment filed 8/10/01 cancelled claims 1-22, a preliminary amendment filed 8/27/01 cancelled claims 23-42 and added claims 43-64. Currently claims 43-64 are pending and have been examined on the merits.

***Specification***

2. Applicant has claimed domestic priority under 35 USC §120 and has noted the co-pending parent cases in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

3. The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. It appears that numerous trademarks have been recited without proper indication (such as ® or ™) after each. Clarification and proper indication of trademarks is required for the

following trademarks used throughout the specification: **NITINOL®**, **ELGILOY®**, & **C-FLEX®**.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 43-48, 51-57, & 60-64** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther et al. (5,329,942) in view of Middleman et al. (5,720,754).

Gunther et al. (hereafter Gunther) teaches of a catheter assembly (10) for use in occluding a vessel and filtering blood in the vessel. The assembly comprises a catheter (30), an expandable member (11) disposed on the distal end of the catheter, and a positioning assembly (12). The positioning assembly acts as the filter actuator. The assembly comprises a central wire (15), seen as the second elongate member, which passes through the catheter, and a sliding lock assembly (23), which also is comprised of a wire (14), and a cannula (22) that slides over the central wire. When the wire guide grasps the central wire, in a frictional manner, the filter is locked in the expanded configuration. The device has a fitting (45) at the proximal end to releasably lock the catheter and filter in the expanded configuration. The wire is longitudinally moved within the catheter to expand the filter. (See col. 3, line 39-col. 7, line 15; figs. 1-5).

Gunther discloses the invention substantially as claimed, however, fails to disclose that the positioning assembly further includes a rotational movement.

Middleman et al. (hereafter Middleman) discloses a device for accessing a vessel in a body comprising a tubular member having a proximal end portion, a distal portion and a lumen therethrough, wherein an expandable member comprises a flexible membrane

that loosely spans a loop of elastically deformable material. The expandable member is a shape memory alloy, which defines an expanded loop in its "memory" shape. The expandable member is constrained within a housing, and the deployment end of the housing is placed within a body. FIG. 3-1 shows a view of the device wherein the housing (10) includes a deployment end which is inserted into the patient and which houses the expandable member in a constrained configuration, a shaft (14), and an actuator (16) opposite end, which is retained substantially outside the patient. A remote actuator means (18) is used to project and/or retract, and, optionally, to rotate the barrier member relative to the distal deployment opening. It is inherent that the rotation step could be carried out while moving the expandable member from expanded to contracted positions.

At the time of the invention, it would have been obvious to substitute the positioning assembly (i.e. actuator) of Gunther with that of Middleman since it is beneficial to have an actuator that will move both longitudinally and rotationally to allow for the exact placement within the vessel of the expandable member and to be able to rotate it if need be to a better position within the vessel.

6. Claims 49, 50, 58, & 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther ('942) and Middleman ('754) in view of Mische et al. (5,490,859). Gunther & Middleman discloses the invention substantially as claimed, see rejection supra, however, fail to disclose specifically the addition of a material that adjoins the expandable member, but does not completely encapsulate said member.

Mische et al. (hereafter Mische) teaches of an intravascular occlusion device comprising a collection portion (220) formed partially over an expandable member (16), either the distal or proximal end, depending on the area where particulate matter to be removed is located in relation to the occlusion. (Col. 23, line 45-col. 27, line 24; figure 17).

It would have been obvious to one having skill in the art, at the time of the invention, to modify the braid apparatus of Gunther & Middleman to add a material to a portion of the expandable member such that said expandable member is partially covered to catch particulate that is removed from the vessel. Blood flow would be allowed to pass through the collection portion of the expandable member yet particulates would be stopped and held within for removal from the vessel.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Huebsch et al. discloses a medical device that is implantable and expandable within a vessel having an actuator device with an actuating.
  
8. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The direct fax number for the examiner is (703) 746-4876. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

pmb *Tricia Bianco*  
March 20<sup>th</sup>, 2003